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HOUSE BILL 232 By
Turner (Dav)

SENATE BILL 203
By Harper

AN ACT to amend Tennessee Code Annotated, Title 56; Title 63 and Title 71, relative to prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. The title of this act is, and may be known and cited as, the "Tennessee Prescription Drug Fair Pricing Act".

SECTION 2.

(a) The general assembly finds that:

(1) Approximately one in four residents of Tennessee have no or wholly inadequate prescription drug insurance coverage.

(2) These uninsured residents pay excessive prices for prescription drugs, far higher prices than are paid by managed care organizations, insurance companies and the federal government for the same medicines and dosages. In many cases, these excessive drug prices have the effect of denying residents access to medically necessary care, and thereby threatening their health and safety.

(3) Many residents require repeated doctor or medical clinic appointments, having gotten sicker because they cannot afford to take the prescriptions prescribed for them. Many residents are admitted to or treated at hospitals each year because they cannot afford the drugs prescribed for them that could have prevented the need for hospitalization. Many others enter expensive institutional care settings because they cannot afford their necessary prescription drugs that could have supported them outside of an institution. In each of these circumstances, state medical assistance programs, including the medical assistance program, literally pay the price.

(4) One major reason uninsured residents pay so much for prescription drugs is that, unlike insured residents, they have no prescription benefits manager negotiating a fair price with the drug companies on their behalf.

(5) The state government currently provides prescription drugs and acts as a prescription benefit manager through a variety of health plans and assistance programs.

(6) The state government is the only agent, as a practical matter, that can play an effective role as a market participant on behalf of all residents who are uninsured or underinsured. The state can and should act as a prescription benefit manager, negotiating voluntary drug rebates and using these funds to reimburse retail pharmacies for offering lower drug prices.

(b) Recognizing that the state already acts as a prescription benefit manager for a variety of health plans and assistance programs, this law is enacted to cover new populations by expanding the state's role as a participant in the prescription drug marketplace, negotiating voluntary rebates from drug companies and using the funds to make prescription drugs more affordable to Tennessee residents. Such a program will

improve public health and welfare, promote the economic strength of our society, and substantially benefit state health assistance programs, including the medical assistance.

SECTION 3.

(a) As used in this section unless the context indicates otherwise:

(1) "Commissioner" means the commissioner of health, or the commissioner's designee(s).

(2) "Department" means the department of health.

(3) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and that has a labeler code from the federal food and drug administration under 21 Code of Federal Regulations, 207.20.

(4) "Manufacturer" means a manufacturer of prescription drugs and includes a subsidiary or affiliate of a manufacturer.

(5) "Participating Retail Pharmacy" means a retail pharmacy or other business licensed to dispense prescription drugs in this state that:

(A) participates in the state medical assistance program, or

(B) voluntarily agrees to participate in the Rx program.

(b)

(1) The Rx program is established within the department to lower prescription drug prices for uninsured and underinsured residents of the state.

(2) A drug manufacturer or labeler that sells prescription drugs in the state may voluntarily elect to enter into a rebate agreement with the department.

(3) The commissioner shall negotiate the terms of the rebate from a manufacturer or labeler, taking into consideration the rebate calculated under the Medicaid Rebate Program pursuant to 42 United States Code, Section 1396r-8,

the average wholesale price of prescription drugs, and any other available information on prescription drug prices and price discounts.

(4) If the commissioner and a drug manufacturer or labeler fail to reach agreement on the terms of a rebate, the commissioner shall prompt a review of whether to place those manufacturer's or labeler's products on the prior authorization list for the state medical assistance program pursuant to Tennessee Code Annotated, Section 71-5-108, and take similar actions involving prior authorization or formularies for any other state-funded prescription drug program. The commissioner shall promulgate rules creating clear procedures for the implementation of this subdivision. The names of manufacturers and labelers that do not enter into rebate agreements are public information and the department shall release this information to the public. The commissioner shall also publicize to doctors, pharmacists, and other health professionals information about the relative cost of drugs produced by manufacturers and labelers that enter into rebate agreements compared to those who do not enter into rebate agreements.

(5) A retail pharmacy shall discount the price of prescription drugs sold to Rx program participants.

(A) The department shall establish discounted prices for drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally-capped drug programs, differential dispensing fees, administrative overhead, and incentive payments.

(B) Beginning July 1, 2001, a retail pharmacy shall offer prescription drugs at or below the average wholesale price, minus six percent (6%), plus a dispensing fee designated by the commissioner.

These initial price levels shall be calculated by the commissioner and the dispensing fee shall not be less than that provided under the state medical assistance program. The average wholesale price is the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug-pricing file.

(C) No later than January 1, 2002, a retail pharmacy shall offer prescription drugs at or below the initial price levels specified in paragraph (B) minus the amount of any rebate paid by the state to the retail pharmacy. These discounted price levels shall be calculated by the commissioner. In determining the discounted price levels, the commissioner shall consider an average of all rebates weighted by sales of drugs subject to these rebates over the most recent twelve (12)-month period for which the information is available.

(6) All residents of the state are eligible to participate in the Rx program. The department shall establish simplified procedures for issuing Rx program enrollment cards to eligible residents. The department shall undertake outreach efforts to build public awareness of the Rx program and maximize enrollment by eligible residents.

(7)

(A) The board of pharmacy shall adopt rules requiring disclosure by retail pharmacies to Rx program participants of the amount of savings provided as a result of the Rx program. The rules must protect information that is proprietary in nature.

(B) The department may not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx program.

(C) A retail pharmacy shall submit claims to the department to verify the amount charged to Rx program participants.

(D) On a weekly or biweekly basis, the department shall reimburse a retail pharmacy for discounted prices provided to Rx program participants and dispensing fees set by the commissioner.

(E) The department shall collect from the retail pharmacies utilization data necessary to calculate the amount of the rebate from the manufacturer or labeler. The department shall protect the confidentiality of all information subject to confidentiality protection under state or federal law, rule or regulation.

(8) Discrepancies in rebate amounts must be resolved using the process established in this subdivision.

(A) If there is a discrepancy in the manufacturer's or labeler's favor between the amount claimed by a pharmacy and the amount rebated by the manufacturer or labeler, the department, at the department's expense, may hire a mutually agreed-upon independent auditor. If a discrepancy still exists following the audit, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the department for any additional amount due.

(B) If there is a discrepancy against the interest of the manufacturer or labeler in the information provided by the department to the manufacturer or labeler regarding the manufacturer's or labeler's rebate, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed-upon independent auditor to verify the accuracy of the data supplied to the department. If a discrepancy still exists following the. audit, the department shall justify the reason for the

discrepancy or refund to the manufacturer any excess payment made by the manufacturer or labeler.

(C) Following the procedures established in paragraph (A) or (B), either the department or the manufacturer or labeler may request a hearing. Supporting documentation must accompany the request for a hearing.

(9) The Tennessee Rx Dedicated Fund, referred to in this section as the "fund," is established to receive revenue from manufacturers and labelers who pay rebates and any appropriations or allocations designated for the fund. The purposes of the fund are to: reimburse retail pharmacies for discounted prices provided to Rx program participants and to reimburse the department for the costs of administering the program, including contracted services, computer costs, professional fees paid to participating retail pharmacies and other reasonable program costs. Moneys from the fund may be expended to fund activities authorized by this part. Any revenues deposited in this reserve shall remain in the reserve until expended for purposes consistent with this part, and shall not revert to the general fund on any June 30. Any excess revenues on interest earned by such revenues shall not revert on any June 30, but shall remain available for appropriation in subsequent fiscal years. Surplus funds in the fund may be used only for the benefit of the program.

(10) The department shall report the enrollment and financial status of the Rx Program to the legislature by the second week in January each year.

(11) In implementing this section, the department shall coordinate with other governmental programs to increase efficiency and, where it is beneficial to another state program, combine drug pricing negotiations to maximize drug rebates for this and other programs, including the state Medicaid program.

(12) The department may adopt rules to implement the provisions of this section in accordance with the provisions of Tennessee Code Annotated, Title 4, Chapter 5.

(13) The department may seek any waivers of federal law, rule or regulation necessary to implement the provisions of this section.

SECTION 4. If any provision of this act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to that end the provisions of this act are declared to be severable.

SECTION 5. For the purposes of rulemaking, this act shall take effect on becoming law and for all other purposes this act shall take effect July 1, 2001, the public welfare requiring it.